Ex. 6

EXHIBIT 6

IND ACKNOWLEDGMENT LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 26 1988

IND 31,861

Warner-Lambert Company
Attention: Donald R. Jaffe, Ph.D.
201 Tabor Road
Morris Plains, New Jersey 07950

Dear Sir/Madam:

We are pleased to acknowledge receipt of your Investigational New Drug Application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act. Please note the following identifying data:

IND number assigned: 31,861

Sponsor: Warner-Lambert Company

Name of Drug: Norethindrone Acetate and Ethinyl Estradiol Tablets, USP

Date of Submission: July 18, 1988

Date of Receipt: July 20, 1988

IT IS UNDERSTOOD THAT STUDIES IN HUMANS WILL NOT BE INITIATED UNTIL 30 DAYS AFTER THE DATE OF RECEIPT SHOWN ABOVE. If, within the 30 day period, we notify you of serious deficiencies that require correction before human studies can begin or that would require restriction of human studies until correction, it is understood that you will continue to withhold or restrict such studies until you are notified that the material you have submitted to correct the deficiencies is satisfactory.

You are responsible for compliance with the Federal Food, Drug and Cosmetic Act and Regulations. This responsibility includes the immediate reporting of any alarming adverse reactions in either animal or human studies, and submission of progress reports at intervals not to exceed one year.

RECEIVED
AUG 18 1988
Regulatory Affairs

As sponsor of the clinical study proposed under this IND, you are now free to obtain supplies of the investigational drug.

Please forward all future communications concerning this IND in TRIPLICATE, IDENTIFIED WITH THIS IND NUMBER and addressed as follows:

Food and Drug Administration
Center for Drug Evaluation and Research, HFD-510
Attention: DOCUMENT CONTROL ROOM 14B03
5600 Fishers Lane
Rockville, Maryland 20857

Should you have any questions concerning this IND, please call me at (301) 443-3490.

Sincerely yours,

EMGalliers

Enid Galliers
Consumer Safety Officer
Division of Metabolism and Endocrine
Drug Products, HFD-510
Center for Drug Evaluation and Research

cc: Dr. R. Buchanan
Dr. K. Kastenholz

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

IND 31,861

AUG 29 1988

Warner-Lambert Co.
Attention: Donald R. Jaffe, Ph.D.
Assistant Director, Regulatory Affairs
201 Tabor Road
Morris Plains, NJ 07950

Dear Dr. Jaffe:

Please refer to your Investigational New Drug Application (IND) submitted pursuant to section 505(i) of the Federal Food, Drug, and Cosmetic Act for the product Estrostep (norethindrone acetate and ethinyl estradiol) Tablets.

We have completed our review of your submission, and your study may proceed. However, we have the following requests for additional information:

1. Please submit a copy of the patient diary that will be used in the study.

2. Please submit the patient consent form(s) to be used in the study.

3. The double-blind investigational drug label which you submitted is not in compliance with our guidelines for Labeling Requirements for Investigational Drugs. Please revise your investigational drug label in accord with the enclosed guidelines.

Your cooperation is appreciated.

Sincerely yours,

Solomon Sobel

Solomon Sobel, M.D.
Director
Division of Metabolism and
Endocrine Drug Products, HFD-510
Center for Drug Evaluation and Research

ENCLOSURE